UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner

v.

STRATUS MEDICAL, LLC,
Patent Owner

Case No. IPR2024-01212
Patent No. 10,925,664

PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE EVIDENCE

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I. INTRODUCTION AND SUMMARY

Stratus hereby opposes the petitioner's motion to exclude (Paper 49, herein "motion" or "Mot.") filed October 17, 2025. The motion wrongly asserts inadmissibility of paragraphs 16-27, 47, 54 and 55 of the declaration of Mr. Cody Jorgensen (Exhibits 2015-2016, "Jorgensen Decl.") and Exhibits 2021-2026 as inadmissible hearsay.

The evidence at issue should not be excluded. "Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well-positioned to determine and assign appropriate weight to evidence presented." *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66 at 19 (May 1, 2014) (citing *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941)). As explained in *Donnelly Garment*:

> [E]xperience has demonstrated that in a trial or hearing where no jury is present, more time is ordinarily lost in listening to arguments as to the admissibility of evidence and in considering offers of proof than would be consumed in taking the evidence proffered. . . . One who is capable of ruling accurately upon the admissibility of evidence is equally capable of sifting it accurately after it has been received, and, since he will base his findings upon the evidence which he regards as competent, material and convincing, he cannot be injured by the presence in the

> record of testimony which he does not consider competent or material.

Donnelly Garment, 123 F.2d at 224; *see also Denso Corp. v. Collision Avoidance Tech. Inc.*, IPR2017-01715, Paper 27 at 30, 31 (Jan. 22, 2019) (expanded panel) (citing *Donnelly* with approval).

So it is here. The petitioner seeks to exclude evidence that proves ***undisputed*** facts, such as the fact that the inventors of the Racz, Fitz, and Lee references are medical doctors, the fact that Stratus received praise, and the facts underlying Stratus's market-share analysis. The petitioner's motion should be promptly denied.

II. THE ADMISSIBILITY OF HEARSAY

Federal Rule of Evidence (FRE) 801 defines hearsay as a statement that "a party offers in evidence to prove the truth of the matter asserted in the statement." FRE 801(c). FRE 803 and 807, among others, set forth exceptions to the rule against hearsay.

But more importantly, relevant hearsay is liberally admitted in administrative hearings, such as this one. The Supreme Court has made clear that the strict hearsay rules used in a traditional court trial do not apply in formal administrative agency adjudications. *See Richardson v. Perales*, 402 U.S. 389, 402 (1971). In *Richardson*, the Supreme Court concluded an administrative agency may rely on hearsay to an extent "reliability and probative value" of the evidence is assured. *Id*.

Indeed, the Board has noted that because a review "proceeding is not a jury trial . . . the risk of prejudice in this forum is less than what may otherwise exist before a jury." *MotionPoint Corp. v. TransPerfect Global, Inc.*, CBM2014-00060, Paper 41 at 22, 23 (July 15, 2015). Here, as explained below, there is "no risk of undue prejudice that would outweigh the probative value of the documents and evidence." *Id.*; *see also Google, Inc. v. Meiresonne*, IPR2014-01188, Paper 38 at 12 (Jan. 20, 2016) ("[W]e admit it and weigh it appropriately . . . [t]his is not a jury trial").

Moreover, even "doubtful" evidence should be admitted so as to form a better record for review on appeal. *See Gnosis S.p.A. v. S. Ala. Med. Sci. Found.*, IPR2013-00118, Paper 64 at 43 (June 20, 2014) ("If the record on review contains not only all evidence which was clearly admissible, but also all evidence of doubtful admissibility, the court which is called upon to review the case can usually make an end of it, whereas if evidence was excluded which that court regards as having been admissible, a new trial or rehearing cannot be avoided."); *see also Sony Computer Entm't Am. LLC v. Game Controller Tech. LLC*, IPR2013-00634, Paper 32 at 31 (Apr. 14, 2015) ("In an *inter partes* review, we regard it as the better course to have a complete record of the evidence to facilitate public access, as well as appellate review.").

Finally, "there is a strong public policy for making all information filed in an administrative proceeding available to the public." *Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.*, CBM2012-00010, Paper 59 at 40 (Feb. 24, 2014); *see also Denso* at 31 (applying that principle to caution against excluding evidence).

Thus, the Board has explained that "[r]ather than excluding evidence that is allegedly hearsay . . ., we will simply not rely on it or give it little or no probative weight, as appropriate, in our analysis." *Denso* at 31.

III. EXHIBITS 2021-24 SHOULD NOT BE EXCLUDED.

Exhibits 2021-2024, which the petitioner wishes to exclude, are biographies of inventors listed in the petitioner's Exhibits 1009-1011, which are the patent documents referred to as Racz, Fitz, and Lee, respectively. Exhibit 2021 is a Wikipedia webpage. Exhibits 2022–2024 are websites promoting each doctor's practice and their public representations. Specifically, Exhibits 2021 and 2022 are biographies of Dr. Gabor Racz (anesthesiologist) and Dr. Philip Finch (pain physician), respectively, who are the inventors of U.S. Patent No. 6,146,380 (Racz, Exhibit 1009). Exhibit 2023 is the biography of Dr. William Fitz (pain physician), who is the inventor of U.S. Patent Publication No. 2005/0059964 (Fitz, Exhibit 1011). Exhibit 2024 is the biography of Dr. Bruce Lee (gynecologist), who is the inventor of U.S. Patent Publication No. 2007/0016183 (Fitz, Exhibit 1010).

Dr. Russo references the inventors' biographies in his declaration. Ex. 2001 ¶¶ 145-47. He indicates "[t]he inventorship of Racz and Fitz is consistent with the qualifications that I deem necessary for a POSITA in the RF neurotomy space" and "the inventorship of Racz, Fitz, and Lee also demonstrates the lack of cross-pollination of RF neurotomy and other specialties, such as gynaecology, in which RF ablation is also employed." *Id*. ¶¶ 146, 147.

Exhibits 2021-2024 show that Racz, Fitz, and Lee held themselves out to be doctors in their respective specialties. That is not disputed. The petitioner has not attacked the veracity of the information in the biographies because the biographies correctly identify the specialties of the doctors. *See* Reply (Paper 30) at 5-7.

Incidentally, Dr. Russo personally knows Dr. Gabor Racz and Dr. Philip Finch, even having been trained on certain RF neurotomy procedures in one-on-one sessions with Dr. Racz. So, Dr. Russo had no need to rely on Exhibits 2021-22, the biographies of these doctors, to know of their specialties. Thus, Exhibits 2021-22 were provided as illustrative support for known and asserted-to facts, rather than as a source of information for those facts. The petitioner could have discovered this fact if it had asked Dr. Russo any questions regarding Dr. Racz during his deposition, but it did not. Nor did it ask any questions regarding Dr. Fitz or Dr. Lee, despite having had an opportunity to do so.

Rule 703 allows a testifying expert to rely on materials, including inadmissible hearsay, in forming the basis of an opinion if the inadmissible hearsay contains facts or data "of a type reasonably relied upon by experts in the particular field." *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993). Although an expert may rely upon inadmissible hearsay, the expert "must form his own opinions by applying his extensive experience and a reliable methodology to his inadmissible materials. Otherwise, the expert is simply repeating hearsay evidence without applying any expertise whatsoever, a practice that allows the [party] to circumvent the rules prohibiting hearsay." *United States v. Mejia*, 545 F.3d 179, 197 (2d Cir. 2008) (quotation marks and internal citations omitted). Dr. Russo applies his lengthy experience as a pain physician to assess the biographies of the doctors and determine their specializations.

To the extent these webpages are considered hearsay, each falls under the residual hearsay exception. FRE 807(a) sets forth the residual exception as follows:

> [A] hearsay statement is not excluded by the rule against hearsay even if the statement is not specifically covered by a hearsay exception in Rule 803 or 804 [if]
>
> (1) the statement is supported by sufficient guarantees of trustworthiness—after considering the totality of circumstances under which it was made and evidence, if any, corroborating the statement;

(2) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts.

Id.

Exhibits 2021-2024 meet these standards because the owners of the websites from which they are drawn have an interest in accurately representing the specialties of the doctors, they are associated with the inventors of the petitioner's primary references, and the doctors' specialties are relevant to the determination of the person of ordinary skill in the art. Due to these hearsay exceptions, there is no reason to exclude Exhibits 2021-24. *See also Ericsson Inc. v. Intellectual Ventures I LLC*, IPR2014-00527, Paper 41 at 11, 12 (May 18, 2015) (applying the hearsay residual exception); *Compass Bank v. Intellectual Ventures I LLC*, IPR2014-00724, Paper 41 at 57-59 (Nov. 5, 2015) (same).

IV. JORGENSEN DECLARATION PARAGRAPHS 53-55 AND EXHIBITS 2025 AND 2026 ARE ADMISSIBLE.

Exhibits 2025 and 2026 are Stratus's press release and website post, respectively, regarding awards recognizing the success of Stratus and its Nimbus product, which is a commercial embodiment of the claimed invention. These awards are discussed in the Jorgensen Declaration. *See* Jorgensen Decl. ¶¶ 53-55. The petitioner argues the exhibits are "out-of-court statements—purporting to report

announcements from Deloitte and Pepperdine University" and thus "should be excluded as hearsay." Mot. at 11.

It is undisputed that Stratus received those two accolades.

Mr. Jorgensen had personal knowledge of the receipt of these awards and provided sworn testimony about the awards. Ex. 2039 ¶¶ 57-59. Mr. Jorgensen discussed the awards during his deposition. Ex. 1047 at 40:13-42:7. Mr. Jorgensen also addressed the reason for including the press releases instead of a document from the award organizer that was just a list of the companies recognized in the particular year. Ex. 1047 at 41:3-12 ("30-some pages of fluff for one little line").

A. Jorgensen Declaration Paragraphs 53-55 and Exhibits 2025 and 2026 Are Not Hearsay.

The petitioner's hearsay objection is without merit because the press release and website post are not offered for the truth of the matters asserted in them, but to show that the statements were made. *See Fox Factory, Inc. v. SRAM, LLC*, IPR2017-01440, Paper 62 at 80 (Dec. 6, 2018). In *Fox Factory*, the Board noted that "[b]ecause the existence of the statements themselves is relevant, 'courts have properly found that articles showing the receipt of 'awards and accolades' are admissible over a hearsay objection." *Id*. (quoting *Asetek Danmark A/S v. CMI USA, Inc.*, No. 13-cv-00457-JST, 2014 WL 12644295, at *2 (N.D. Cal. Nov. 19, 2014)

(collecting cases)). On at least this basis, the press releases and related paragraphs of the Jorgensen Declaration are relevant.

B. Hearsay Exceptions Apply Even If Jorgensen Declaration Paragraphs 53-55 and Exhibits 2025 and 2026 Are Considered Hearsay.

Even if the Jorgensen Declaration ¶¶ 53-55 and Exhibits 2025 and 2026 are hearsay, they are admissible under FRE 803(6) and 807, the business records and residual exceptions to the hearsay rule. With respect to FRE 803(6), the press release and website post are admissible because Mr. Jorgensen is a qualified witness and the press releases are records of a regularly conducted business activity. These items also fall under the residual exception because Mr. Jorgensen's testimony provides sufficient guarantees of its trustworthiness, the petitioner has failed to present any meaningful doubt as to its trustworthiness, and it is highly probative to the issue. *See, e.g., United States v. Turner*, 718 F. 3d 226, 233-35 (3d Cir. 2013). "[T]he theory of the hearsay rule . . . is that the many possible sources of inaccuracy and untrustworthiness which may lie underneath the bare untested assertion of a witness can best be brought to light and exposed, if they exist, by the test of cross-examination." *In re Epstein*, 32 F.3d 1559, 1565 (Fed. Cir. 1994) (quoting 5 John H. Wigmore, Evidence in Trials at Common Law § 1420, at 250). The petitioner cross-examined Mr. Jorgensen in this proceeding and elected to forego any questions

that addressed the trustworthiness of Mr. Jorgensen's testimony regarding these awards.

V. JORGENSEN DECLARATION PARAGRAPHS 16-27 AND 47 ARE ADMISSIBLE.

As stated in his declaration, Mr. Jorgensen is Stratus's Director of Marketing, has been in marketing roles with Stratus for six years, assisted with the launch of the Nimbus device, and has closely followed the market performance of Stratus and its competitors since the introduction of the Nimbus device. Jorgensen Declaration ¶¶ 4-6, 13-27; *see also* Ex. 1047 at 12:12-16:7, 69:13-75:6, 80:15-96:5. The petitioner alleges that paragraphs 16-27 and 47 of his declaration are inadmissible under FRE 602 and/or 802 because Mr. Jorgensen relies on hearsay. These paragraphs include statements comparing the U.S. RFA cannula market share of Stratus, the petitioner, and other competitors in that market, as well as information regarding sales-force sizes.

In the petitioner's request for additional discovery, the petitioner requested "all documents and electronically stored information relied on by Cody Jorgensen to prepare the information in paragraphs 16 through 27 (and the associated charts and graphics) of his declaration." Paper 19 at 3. Stratus responded that the request was "far too broad and non-specific." Paper 21 at 6. The petitioner did not follow up during the deposition of Mr. Jorgensen to ask him to specifically identify his

sources of information for the sales data of the petitioner, *see* Ex. 1047 at 69:13-72:18 and 91:18-96:5, or other competitors in the U.S. RFA cannula market, *see id*. at 72:19-75:6 and 85:10-91:17; nor did it ask him to specifically identify his sources for information regarding sales force sizes, *see id*. at 75:7-80:14.

The petitioner had every opportunity to contest the accuracy of Mr. Jorgensen's underlying data. Indeed, the petitioner went to great lengths questioning whether Mr. Jorgensen could have possibly known the confidential information of other companies in the U.S. RFA cannula market. One of those companies is Avanos, the petitioner. The petitioner had access to its own sales and sales force data, it could have easily undermined Mr. Jorgensen's market data by showing inconsistencies between that data and the petitioner's actual data. But the petitioner provided no such conflicting data. The petitioner opted instead to provide data regarding its COOLIEF* device, a device that was excluded from the U.S. RFA cannula market, which has no bearing on the accuracy of Mr. Jorgensen's data regarding the petitioner's products that were included in the U.S. RFA cannula market.

In summary, after asking for and failing to obtain broad discovery, the petitioner chose not to ask for specific information from Mr. Jorgensen regarding his sworn statements. And the petitioner then failed to contradict Mr. Jorgensen's sworn statements. For example, if the information provided by Mr. Jorgensen regarding

the market share or sales force size of the petitioner were inaccurate, then the petitioner could have easily countered Mr. Jorgensen's statements in its Reply.

A. Hearsay Exceptions Apply Even if Paragraphs 16-27 and 47 of the Jorgensen Declaration Are Considered Hearsay.

Mr. Jorgensen's statements in paragraphs 16-27 and 47 are relevant to commercial success as an objective indicia of nonobviousness. These statements regarding comparative market data in Mr. Jorgensen's declaration fall under the residual exception of FRE 807.

FRE 807 allows hearsay evidence to be admitted even if it does not explicitly fall within an established exception as long as the evidence is supported by sufficient guarantees of trustworthiness and is more probative than other evidence reasonably available. *See* FRE 807(a). Paragraphs 16-27 and 47 of the Jorgensen Declaration meet these standards. The fact that Mr. Jorgensen's made the statements in a sworn declaration is a indication of trustworthiness. Ex. 2039 ¶¶ 57-59. Additionally, the petitioner deposed Mr. Jorgensen extensively regarding the statements, including his statements related to the comparative market data. Ex. 1047 at 69:13-72:18, 72:19-75:6, and 85:10-91:17. The same applies to the sales-force data. *Id*. at 75:7-80:14. Following the deposition, the petitioner provided no rationale in its Reply to question the trustworthiness of Mr. Jorgensen's statements.

In his deposition, Mr. Jorgensen explained that the comparative market data includes confidential information of Stratus and public information from other companies presented together as accurately as possible. *Id*. at 86:5-90:14. The deposition makes it clear that the comparative market data is more probative regarding commercial success on the point for which it is offered than any other evidence that Stratus can obtain through reasonable efforts. *Id*. For example, Mr. Jorgensen explained how he obtained market-share data for public companies during investor calls, compiled that information, and used it to verify details. *Id*. at 89:9-90:14. He was asked to confirm that such companies "don't share all of the information about exactly what they're selling and how much they're selling for their US RFA cannula market," and he conceded that point. *Id*. at 90:4-11. Thus, his deposition provides circumstantial guarantees of trustworthiness and establishes that his analysis is more probative on the point for which it is offered than any other evidence that Stratus can obtain through reasonable efforts.

Under the petitioner's assertions, virtually every market analysis would be inadmissible hearsay because the most accurate information regarding each company's market share may not be publicly available. If such market data analyses were always excluded as hearsay, few circumstances would permit information regarding commercial success to ever be independently admissible. On this basis, admitting paragraphs 16-27 and 47 of the Jorgensen Declaration will best serve the

interests of justice. Because the factors for the residual exception are met, there is no reason to exclude paragraphs 16-27 and 47 of the Jorgensen Declaration.

B. Even If No Hearsay Exception Applies, the Jorgensen Declaration Should be Admitted.

According to the Supreme Court, an important factor in assessing the "reliability and probative value" of hearsay evidence is the opportunity to depose the witness. *See Richardson*, 402 U.S. at 402. Here, the petitioner deposed Mr. Jorgensen and had a full and fair opportunity to explore the basis for his testimony in the paragraphs in question.

VI. CONCLUSION

For at least the foregoing reasons, Stratus respectfully requests that the Board deny the petitioner's motion to exclude evidence and consider the entirety of Exhibit 2015 and Exhibits 2021-2026.

Respectfully submitted,

Date: 2025 Oct. 24

By: /M.C. Phillips/
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CERTIFICATE OF SERVICE

I hereby certify that on October 24, 2025, copies of the foregoing PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE EVIDENCE and all documents filed with it were served via electronic mail, as agreed to by counsel, upon the following counsel for the petitioner:

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